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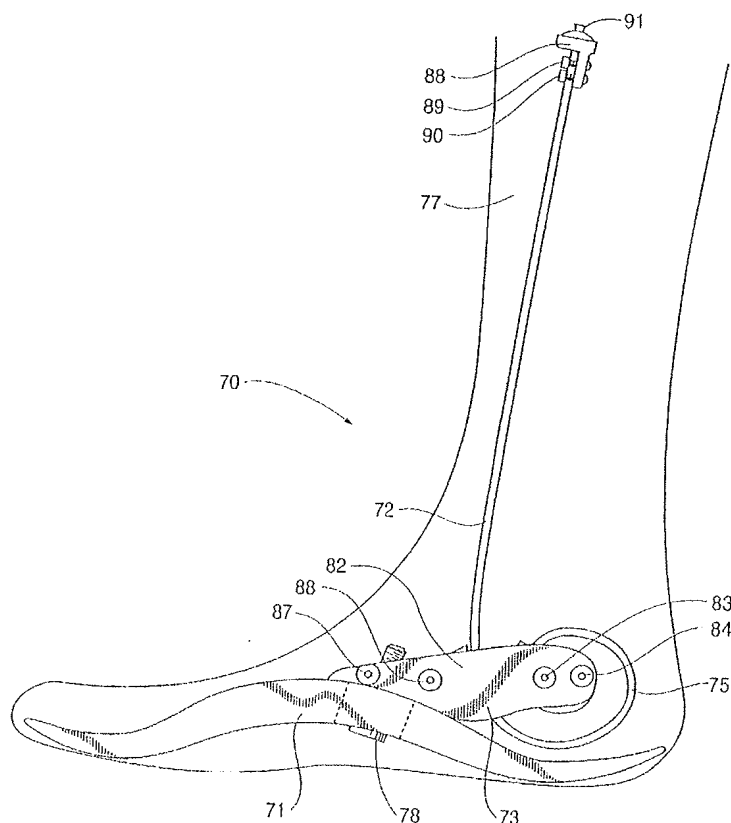
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(54) Title: PROSTHETIC FOOT WITH TUNABLE PERFORMANCE



(57) Abstract: A prosthetic foot (70) incorporates a foot keel (71) and a calf shank (72) connected to the foot keel to form an ankle joint area of the prosthetic foot. The foot keel has forefoot and hindfoot portions and an upwardly arched midfoot portion extending between the forefoot and midfoot portions. The calf shank includes a downward convexly curved lower end in the form of a spiral which is adjustably attached at a portion thereof to the foot keel by way of a coupling element. The calf shank extends upward anteriorly from the spiral to an upstanding upper end thereof. The coupling element includes a stop of a predetermined size to limit dorsiflexion of the calf shank in gait. The calf shank creates an integrated ankle and calf shank with the foot keel which has a variable radii response outcome similar to the disclosed parabola shaped calf shank while being readily covered by a cosmetic covering for the foot, ankle and lower leg.

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PROSTHETIC FOOT WITH TUNABLE PERFORMANCE

TECHNICAL FIELD

5 The present invention relates to a high performance prosthetic foot providing improved dynamic response capabilities as these capabilities relate to applied force mechanics.

BACKGROUND ART

10 A jointless artificial foot for a leg prosthesis is disclosed by Martin et al. in U.S. Patent No. 5,897,594. Unlike earlier solutions wherein the artificial foot has a rigid construction provided with a joint in order to imitate the function of the ankle, the jointless artificial foot of Martin et al. employs a resilient foot insert which is arranged inside a foot molding. The insert is of approximately C-shaped design in longitudinal section, with the opening to the rear, and takes up the prosthesis load with its upper C-limb and via its lower C-limb transmits that load to a leaf spring connected thereto. The leaf spring as seen from the underside is of convex design and extends approximately parallel to the sole region, forward beyond the foot insert into the foot-tip region. The Martin et al. invention is based on the object of improving the jointless artificial foot with regard to damping the impact of the heel, the elasticity, the heel-to-toe walking and the lateral stability, in order thus to permit the wearer to walk in a natural manner, the intention being to allow the wearer both to walk normally and also to carry out physical exercise and to play sports. However, the dynamic response characteristics of this known artificial foot are limited. There is a need for a higher performance prosthetic foot having improved applied mechanics design features which can improve amputee athletic performances involving activities such as running, jumping, sprinting, starting, 15 stopping and cutting, for example.

Other prosthetic feet have been proposed by Van L. Phillips which allegedly provide an amputee with an agility and mobility to engage in a wide variety of activities which were precluded in the past because of the structural limitations and

corresponding performances of prior art prostheses. Running, jumping and other activities are allegedly sustained by these known feet which, reportedly, may be utilized in the same manner as the normal foot of the wearer. See U.S. Patent Nos. 6,071,313; 5,993,488; 5,899,944; 5,800,569; 5,800,568; 5,728,177; 5,728,176; 5,824,112; 5,593,457 5,514,185; 5,181,932; and 4,822,363, for example.

DISCLOSURE OF INVENTION

In order to allow the amputee athlete to attain a higher level of performance, there is a need for a high performance prosthetic foot having improved applied mechanics, which foot can out perform the human foot and also out perform the prior art prosthetic feet. It is of interest to the amputee athlete to have a high performance prosthetic foot having improved applied mechanics, high low dynamic response, and alignment adjustability that can be fine tuned to improve the horizontal and vertical components of activities which can be task specific in nature.

The prosthetic foot of the present invention addresses these needs. According to an example embodiment disclosed herein, the prosthetic foot of the invention comprises a longitudinally extending foot keel having a forefoot portion at one end, a hindfoot portion at an opposite end and a relatively long midfoot portion extending between and upwardly arched from the forefoot and hindfoot portions. A calf shank including a downward convexly curved lower end is also provided. An adjustable fastening arrangement attaches the curved lower end of the calf shank to the upwardly arched midfoot portion of the foot keel to form an ankle joint area of the prosthetic foot.

The adjustable fastening arrangement permits adjustment of the alignment of the calf shank and the foot keel with respect to one another in the longitudinal direction of the foot keel for tuning the performance of the prosthetic foot. By adjusting the alignment of the opposed upwardly arched midfoot portion of the foot keel and the downward convexly curved lower end of the calf shank with respect to one another in the longitudinal direction of the foot keel, the dynamic response characteristics and motion outcomes of the foot are changed to be task specific in relation to the

needed/desired horizontal and vertical linear velocities. A multi-use prosthetic foot is disclosed having high and low dynamic response capabilities, as well as biplanar motion characteristics, which improve the functional outcomes of amputees participating in sporting and/or recreational activities. A prosthetic foot especially for sprinting is also disclosed.

The calf shank in one embodiment has its lower end in the form of a spiral with the calf shank extending upward anteriorly from the spiral to an upstanding upper end thereof. This creates a calf shank with an integrated ankle at the lower end thereof, when the calf shank is secured to the foot keel, with a variable radii response outcome similar to a parabola-shaped calf shank of the invention. The calf shank with spiral lower end is secured to the foot keel by way of a coupling element. In the disclosed embodiment the coupling element includes a stop to limit dorsiflexion of the calf shank in gait.

These and other objects, features and advantages of the present invention become more apparent from a consideration of the following detailed description of disclosed example embodiments of the invention and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration representing the two adjacent radii of curvatures R_1 and R_2 , one against the other, of a foot keel and calf shank of a prosthetic foot of the invention which creates a dynamic response capability and motion outcome of the foot in gait in the direction of arrow B which is perpendicular to the tangential line A connecting the two radii.

Fig. 2 is a view similar to Fig. 1 but showing the alignment of the two radii having been changed in the prosthetic foot according to the invention to increase the horizontal component and decrease the vertical component of the dynamic response capability and motion outcome of the foot in gait so that arrow B_1 , perpendicular to tangential line A_1 , is more horizontally directed than is the case depicted in Fig. 1.

Fig. 3 is a side view of a prosthetic foot according to an example embodiment of the invention with pylon adapter and pylon connected thereto for securing the foot to the lower leg of an amputee.

Fig. 4 is a front view of the prosthetic foot with pylon adapter and pylon of Fig. 3.

5 Fig. 5 is a top view of the embodiment of Figs. 3 and 4.

Fig. 6 is a side view of another foot keel of the invention, especially for sprinting, which may be used in the prosthetic foot of the invention.

Fig. 7 is a top view of the foot keel of Fig. 6.

0 Fig. 8 is a bottom view of the foot keel in the prosthetic foot in Fig. 3 which provides high low dynamic response characteristics as well as biplanar motion capabilities.

Fig. 9 is a side view of an additional foot keel of the invention for the prosthetic foot particularly useful for sprinting by an amputee that has had a Symes amputation of the foot.

5 Fig. 10 is a top view of the foot keel of Fig. 9.

Fig. 11 is a further variation of foot keel for the prosthetic foot of the invention for a Symes amputee, the foot keel providing the prosthetic foot with high low dynamic response characteristics as well as biplanar motion capabilities.

Fig. 12 is a top view of the foot keel of Fig. 11.

0 Fig. 13 is a side view of a foot keel of the invention wherein the thickness of the keel tapers, e.g., is progressively reduced, from the midfoot portion to the hindfoot portion of the keel.

Fig. 14 is a side view of another form of the foot keel wherein the thickness tapers from the midfoot toward both the forefoot and hindfoot of the keel.

5 Fig. 15 is a side view from slightly above and to the front of a parabola shaped calf shank of the prosthetic foot of the invention, the thickness of the calf shank tapering toward its upper end.

Fig. 16 is a side view like Fig. 15 but showing another calf shank tapered from the middle towards both its upper and lower ends.

Fig. 17 is a side view of a C-shaped calf shank for the prosthetic foot, the calf shank thickness tapering from the middle towards both its upper and lower ends.

Fig. 18, is a side view of another example of a C-shaped calf shank for the prosthetic foot, the thickness of the calf shank being progressively reduced from its midportion to its upper end.

Fig. 19 is a side view of an S-shaped calf shank for the prosthetic foot, both ends being progressively reduced in thickness from the middle thereof.

Fig. 20 is a further example of an S-shaped calf shank which is tapered in thickness only at its upper end.

Fig. 21 is a side view of a J-shaped calf shank, tapered at each end, for the prosthetic foot of the invention.

Fig. 22 is a view like Fig. 21 but showing a J-shaped calf shank which is progressively reduced in thickness towards only its upper end.

Fig. 23 is a side view, from slightly above, of a metal alloy or plastic coupling element used in the adjustable fastening arrangement of the invention for attaching the calf shank to the foot keel as shown in Fig. 3.

Fig. 24 is a view from the side and slightly to the front of a pylon adapter used on the prosthetic foot of Figs. 3-5, and also useful with the foot of Figs. 28 and 29, for connecting the foot to a pylon to be attached to an amputee's leg.

Fig. 25 is a side view of another prosthetic foot of the invention similar to that in Fig. 3, but showing use of a coupling element with two releasable fasteners spaced longitudinally connecting the element to the calf shank and foot keel, respectively.

Fig. 26 is an enlarged side view of the coupling element in Fig. 25.

Fig. 27 is an enlarged side view of the calf shank of the prosthetic foot of Fig. 25.

Fig. 28 is a side view of another embodiment of the prosthetic foot wherein the calf shank is utilized within a cosmetic covering of the foot.

Fig. 29 is a top view of the prosthetic foot in Fig. 28.

Fig. 30 is a cross-sectional view of the prosthetic foot of Figs. 28 and 29 taken along the line 30-30 in Fig. 29.

Fig. 31A and 31B are sectional views of wedges of different thicknesses which may be used in the dorsiflexion stop of the coupling element as shown in Fig. 30.

BEST MODE FOR CARRYING OUT THE INVENTION

5 Referring now to the drawings, a prosthetic foot 1 in the example embodiment of Figures 3-5 is seen to comprise a longitudinally extending foot keel 2 having a forefoot portion 3 at one end, a hindfoot portion 4 at an opposite end and an upwardly arched midfoot portion 5 extending between the forefoot and hindfoot portions. The midfoot portion 5 is upward convexly curved over its entire longitudinal extent between the
.0 forefoot and hindfoot portions in the example embodiment.

An upstanding calf shank 6 of the foot 1 is attached at a portion of a downward convexly curved lower end 7 thereof to a proximate, posterior surface of the keel midfoot portion 5 by way of a releasable fastener 8 and coupling element 11. The fastener 8 is a single bolt with nut and washers in the example embodiment, but could
5 be a releasable clamp or other fastener for securely positioning and retaining the calf shank on the foot keel when the fastener is tightened.

A longitudinally extending opening 9 is formed in a proximate, posterior surface of the keel midfoot portion 5, see Figure 8. A longitudinally extending opening 10 is also formed in the curved lower end 7 of the calf shank 6 like that shown in Figure 15, for
0 example. The releasable fastener 8 extends through the openings 9 and 10 which permit adjusting the alignment of the calf shank and the foot keel with respect to one another in the longitudinal direction, A-A in Figure 5, when the fastener 8 is loosened or released for tuning the performance of the prosthetic foot to be task specific. Thus, the fastener 8, coupling element 11 and longitudinally extending openings 9 and 10
5 constitute an adjustable fastening arrangement for attaching the calf shank to the foot keel to form an ankle joint area of the prosthetic foot.

The effects of adjusting the alignment of the calf shank 6 and foot keel 2 are seen from a consideration of Figures 1 and 2, wherein the two radii R_1 and R_2 , one next to another, represent the adjacent, facing, domed or convexly curved surfaces of the

foot keel midportion 5 and the calf shank 6. When two such radii are considered one next to another, motion capability exists perpendicular to a tangential line, A in Figure 1, A₁ in Figure 2, drawn between the two radii. The interrelationship between these two radii determines a direction of motion outcomes. As a consequence, dynamic response force application of the foot 1 is dependent on this relationship. The larger the radius of a concavity, the more dynamic response capability. However, the tighter a radius, the quicker it responds.

The alignment capability of the calf shank and foot keel in the prosthetic foot of the invention allows the radii to be shifted so that horizontal or vertical linear velocities with the foot in athletic activities are affected. For example, to improve the horizontal linear velocity capability of the prosthetic foot 1, an alignment change can be made to affect the relationship of the calf shank's radius and the foot keel radius. That is, to improve the horizontal linear velocity characteristic, the bottom radius R₂, of the foot keel, is made more distal than its start position, Figure 2 as compared with Figure 1. This changes the dynamic response characteristics and motion outcomes of the foot 1 to be more horizontally directed and as a result greater horizontal linear velocity can be achieved with the same applied forces.

The amputee can, through practice, find a setting for each activity that meets his/her needs as these needs relate to horizontal and vertical linear velocities. A jumper and a basketball player, for example, need more vertical lift than a sprint runner. The coupling element 11 is a plastic or metal alloy alignment coupling (see Figures 3, 4 and 23) sandwiched between the attached foot keel 2 and calf shank 6. The releasable fastener 8 extends through a hole 12 in the coupling element. The coupling element extends along the attached portion of the calf shank and the proximate, posterior surface of the keel midfoot portion 5.

The curved lower end 7 of the calf shank 6 is in the shape of a parabola with the smallest radius of curvature of the parabola located at the lower end and extending upwardly, and initially anteriorly in the parabola shape. A posteriorly facing concavity is formed by the curvature of the calf shank as depicted in Figure 3. The parabola shape is

advantageous in that it has increased dynamic response characteristics in creating both improved horizontal linear velocity associated with the relatively larger radii proximal terminal end thereof, while having a smaller radius of curvature at its lower end for quicker response characteristics. The larger radii of curvature at the upper end of the parabola shape enable the tangential line A, explained with reference to Figures 1 and 2, to remain more vertically oriented with changes in alignment, which creates improved horizontal linear velocity.

The parabolic shaped calf shank responds to initial contact ground forces in human gait by compressing or coiling in on itself. This makes the radii of the parabola curve smaller, and as a consequence, the resistance to compression is decreased. In contrast, as the parabolic shaped calf shank responds to heel off ground reaction forces (GRFs) in human gait by expanding, this makes the radii of the parabola curve larger and as a consequence resistance is much greater than the aforementioned compressive resistance. These resistances are associated with the human's anterior and posterior calf muscle function in human gait. At initial contact to foot flat of human gait, the smaller anterior calf muscle group responds to GRFs by eccentrically contracting to lower the foot to the ground and a dorsiflexion moment is created. From foot flat to toe off the larger posterior calf muscle group responds to GRFs also by eccentrically contracting and a greater plantar flexion moment is created. This moment size relates to the calf anterior and posterior muscle group difference in size. As a consequence, the prosthetic calf shank's resistance to the dorsiflexion and plantar flexion moments in human gait are mimicked and normal gait is achieved. The parabolic curves variable resistance capability mimics the human calf musculature function in human gait and running and jumping activities, and as a consequence prosthetic efficiency is achieved.

A human being walks at approximately three miles per hour. A 4:00 minute miler runs at 12 miles per hour and a 10 second, 100 meter sprinter sprints at 21 miles per hour. This is a 1 to 4 to 7 ratio. The horizontal component of each task is greater as the velocity of the activity increases. As a consequence, the size of the prosthetic calf

shank radii can be predetermined. A walker needs a smaller radii parabolic curved calf shank than a miler and a sprinter. A sprint runner needs a parabolic curved calf shank that is seven times as large. This relationship shows how to determine the parabolic radii for walkers, runners and sprinters. It is of significance because sprint runners have
5 increased range of motion requirements and their calf shanks must be stronger to accept the increased loads associated with this activity. A wider or larger parabolic calf shank will be a relatively flatter curve, which equates to greater structural strength with increased range of motion.

A pylon adapter 13 is connected to the upper end of the calf shank 6 by
10 fasteners 14. The adapter 13 in turn is secured to the lower end of pylon 15 by fasteners 16. Pylon 15 is secured to the lower limb of the amputee by a supporting structure (not shown) attached to the leg stump.

The forefoot, midfoot and hindfoot portions of the foot keel 2 are formed of a single piece of resilient material in the example embodiment. For example, a solid piece
5 of material, plastic in nature, having shape-retaining characteristics when deflected by the ground reaction forces can be employed. More particularly, the foot keel and also the calf shank can be formed of laminated composite material having reinforcing fiber laminated with polymer matrix material. In particular, a high strength graphite, laminated with epoxy thermosetting resins, or extruded plastic utilized under the
10 tradename of Delran, or degassed polyurethane copolymers, may be used to form the foot keel and also the calf shank. The functional qualities associated with these materials afford high strength with low weight and minimal creep. The thermosetting epoxy resins are laminated under vacuum utilizing prosthetic industry standards. The polyurethane copolymers can be poured into negative molds and the extruded plastic
5 can be machined. Each material of use has its advantages and disadvantages. It has been found that the laminated composite material for the foot keel and the calf shank can also advantageously be a thermo-formed (prepreg) laminated composite material manufactured per industry standards, with reinforcing fiber and a thermoplastic polymer matrix material for superior mechanical expansion qualities. A suitable commercially

available composite material of this kind is CYLON® made by Cytec Fiberite Inc. of Havre de Grace, Maryland.

5 The resilient material's physical properties as they relate to stiffness, flexibility and strength are all determined by the thickness of the material. A thinner material will
deflect easier than a thicker material of the same density. The material utilized, as well
as the physical properties, are associated with the stiffness to flexibility characteristics in
the prosthetic foot keel and calf shank. The thickness of the foot keel and calf shank are
uniform or symmetrical in the example embodiment of Figures 3-5, but the thickness
along the length of these components can be varied as discussed below, such as by
0 making the hindfoot and forefoot areas thinner and more responsive to deflection in the
midfoot region.

To aid in providing the prosthetic foot 1 with a high low dynamic response
capability, the midfoot portion 5 is formed by a longitudinal arch such that the medial
aspect of the longitudinal arch has a relatively higher dynamic response capability than
5 the lateral aspect of the longitudinal arch. For this purpose, in the example embodiment,
the medial aspect of the longitudinal arch concavity is larger in radius than the lateral
aspect thereof.

The interrelationship between the medial to lateral radii size of the longitudinal
arch concavity of the midfoot portion 5 is further defined as the anterior posterior plantar
surface weight bearing surface areas of the foot keel 2. The line T_1 - T_2 on the anterior
section of 5 in Fig. 8 represents the anterior plantar surface weight bearing area. Line
 P_1 - P_2 represents the posterior plantar weight-bearing surface of 5. The plantar weight
bearing surfaces on the lateral side of the foot would be represented by the distance
between T_1 - P_1 . The plantar weight bearing surfaces on the medial side of the foot 2 are
represented by the distance between P_2 - T_2 . The distances represented by T_1 - P_1 and
3 P_2 - T_2 determine the radii size, and as a result the high low dynamic response
interrelationship is determined and can be influenced by converging or diverging these
two lines T_1 - T_2 to P_1 - P_2 . As a result, high low dynamic response can be determined in
structural design.

The posterior end 17 of the hindfoot portion 4 is shaped in an upwardly curved arch that reacts to ground reaction forces during heel strike by compressing for shock absorption. The heel formed by the hindfoot portion 4 is formed with a posterior lateral corner 18 which is more posterior and lateral than the medial corner 19 to encourage hindfoot eversion during initial contact phase of gait. The anterior end 20 of the forefoot portion 3 is shaped in an upwardly curved arch to simulate the human toes being dorsiflexed in the heel rise toe off position of the late stance phase of gait. Rubber or foam pads 53 and 54 are provided on the lower forefoot and hindfoot as cushions.

Improved biplanar motion capability of the prosthetic foot is created by medial and lateral expansion joint holes 21 and 22 extending through the forefoot portion 3 between dorsal and plantar surfaces thereof. Expansion joints 23 and 24 extend forward from respect ones of the holes to the anterior edge of the forefoot portion to form medial, middle and lateral expansion struts 25-27 which create improved biplanar motion capability of the forefoot portion of the foot keel. The expansion joint holes 21 and 22 are located along a line, B-B in Figure 5, in the transverse plane which extends at an angle α of 35° to the longitudinal axis A-A of the foot keel with the medial expansion joint hole 21 more anterior than the lateral expansion joint hole 22.

The angle α of line B-B to longitudinal axis A-A in Figure 5 can be as small as 15° and still derive a high low dynamic response. As this angle α changes, so should the angle Z of the line T₁-T₂ in Figure 8. The expansion joint holes 21 and 22 as projected on a sagittal plane are inclined at an angle of 45° to the transverse plane with the dorsal aspect of the holes being more anterior than the plantar aspect. With this arrangement, the distance from the releasable fastener 8 to the lateral expansion joint hole 22 is shorter than the distance from the releasable fastener to the medial expansion joint hole 21 such that the lateral portion of the prosthetic foot 1 has a shorter toe lever than the medial for enabling midfoot high and low dynamic response. In addition, the distance from the releasable fastener 8 to the lateral plantar weight bearing surface as represented by T₁, line is shorter than the distance from the releasable fastener to the medial plantar surface weight bearing surface as represented by the line T₂ - such that

the lateral portion of the prosthetic foot 1 has a shorter toe lever than the medial for enabling midfoot high low dynamic response.

5 The anterior of the hindfoot portion 4 of the foot keel 2 further includes an expansion joint hole 28 extending through the hindfoot portion 4 between dorsal and plantar surfaces thereof. An expansion joint 29 extends posteriorly from the hole 28 to the posterior edge of the hindfoot portion to form expansion struts 30 and 31. These create improved biplanar motion capability of the hindfoot portion of the foot.

0 A dorsal aspect of the midfoot portion 5 and the forefoot portion 3 of the foot keel 2 form the upwardly facing concavity, 32 in Figure 3, so that it mimics in function the fifth ray axis of motion of a human foot. That is, the concavity 32 has a longitudinal axis C-C which is oriented at an angle β of 15° to 35° to the longitudinal axis A-A of the foot keel with the medial being more anterior than the lateral to encourage fifth ray motion in gait as in the oblique low gear axis of rotation of the second to fifth metatarsals in the human foot.

5 The importance of biplanar motion capability can be appreciated when an amputee walks on uneven terrain or when the athlete cuts medially or laterally on the foot. The direction of the ground force vector changes from being sagittally oriented to having a frontal plane component. The ground will push medially in opposite direction to the foot pushing laterally. As a consequence to this, the calf shank leans medially and weight is applied to the medial structure of the foot keel. In response to these pressures, the medial expansion joint struts 25 and 31 of the foot keel 2 dorsiflex (deflect upward) and invert, and the lateral expansion joint struts 27 and 30 plantar flex (deflect downwards) and evert. This motion tries to put the plantar surface of the foot flat on the ground (plantar grade).

5 Another foot keel 33 of the invention, especially for sprinting, may be used in the prosthetic foot of the invention, see Figures 6 and 7. The body's center of gravity in a sprint becomes almost exclusively sagittal plane oriented. The prosthetic foot does not need to have a low dynamic response characteristic. As a consequence, the 15° to 35° external rotation orientation of the longitudinal axis of the forefoot, midfoot concavity as

in foot keel 2 is not needed. Rather, the concavity's longitudinal axis D-D orientation should become parallel to the frontal plane as depicted in Figures 6 and 7. This makes the sprint foot respond in a sagittal direction only. Further, the orientation of the expansion joint holes 34 and 35 in the forefoot and midfoot portions, along line E-E, is parallel to the frontal plane, i.e., the lateral hole 35 is moved anteriorly and in line with the medial hole 34 and parallel to the frontal plane. The anterior terminal end 36 of the foot keel 33 is also made parallel to the frontal plane. The posterior terminal heel area 37 of the foot keel is also parallel to the frontal plane. These modifications effect in a negative way the multi-use capabilities of the prosthetic foot. However, its performance characteristics become task specific. Another variation in the sprint foot keel 33 is in the toe, ray region of the forefoot portion of the foot where 15° of dorsiflexion in the foot keel 2 are increased to 25-40° of dorsiflexion in foot keel 33.

Figures 9 and 10 show an additional foot keel 38 of the invention for the prosthetic foot particularly useful for sprinting by an amputee that has had a Symes amputation of the foot. For this purpose, the midfoot portion of the foot keel 38 includes a posterior, upwardly facing concavity 39 in which the curved lower end of the calf shank is attached to the foot keel by way of the releasable fastener. This foot keel can be utilized by all lower extremity amputees. The foot keel 38 accommodates the longer residual limb associated with the Symes level amputee. Its performance characteristics are distinctively quicker in dynamic response capabilities. Its use is not specific to this level of amputation. It can be utilized on all transtibial and transfemoral amputations. The foot keel 40 in the example embodiment of Figures 11 and 12 also has a concavity 41 for a Symes amputee, the foot keel providing the prosthetic foot with high low dynamic response characteristic as well as biplanar motion capabilities like those of the example embodiment in Figures 3-5 and 8.

The functional characteristics of the several foot keels for the prosthetic foot 1 are associated with the shape and design features as they relate to concavities, convexities, radii size, expansion, compression, and material physical properties - all of

these properties relating, to reacting to, ground forces in walking, running and jumping activities.

The foot keel 42 in Figure 13 is like that in the example embodiment of Figures 3-5 and 8, except that the thickness of the foot keel is tapered from the midfoot portion to the posterior of the hindfoot. The foot keel 43 in Figure 14 has its thickness progressively reduced or tapered at both its anterior and posterior ends. Similar variations in thickness are shown in the calf shank 44 of Figure 15 and the calf shank 45 of Figure 16 which may be used in the prosthetic foot 1. Each design of the foot keel and calf shank create different functional outcomes, as these function outcomes relate to the horizontal and vertical linear velocities which are specific to improving performance in varied athletic related tasks. The capability of multiple calf shank configurations and adjustments in settings between the foot keel and the calf shank create a prosthetic foot calf shank relationship that allows the amputee and/or the prosthetist the ability to tune the prosthetic foot for maximum performance in a selected one of a wide variety of sport and recreational activities.

Other calf shanks for the prosthetic foot 1 are illustrated in Figures 17-22 and include C-shaped calf shanks 46 and 47, S-shaped calf shanks 48 and 49 and J-shaped calf shanks 50 and 51. The upper end of the calf shank could also have a straight vertical end with a pyramid attachment plate attached to this proximal terminal end. A male pyramid could be bolted to and through this vertical end of the calf shank. Plastic or aluminum fillers to accept the proximal male pyramid and the distal foot keel could also be provided in the elongated openings at the proximal and distal ends of the calf shank. The prosthetic foot of the invention is a modular system preferably constructed with standardized units or dimensions for flexibility and variety in use.

All track related running activities take place in a counter-clockwise direction. Another, optional feature of the invention takes into account the forces acting on the foot advanced along such a curved path. Centripetal acceleration acts toward the center of rotation where an object moves along a curved path. Newton's third law is applied for energy action. There is an equal and opposite reaction. Thus, for every "center seeking"

force, there is a "center fleeing" force. The centripetal force acts toward the center of rotation and the centrifugal force, the reaction force, acts away from the center of rotation. If an athlete is running around the curve on the track, the centripetal force pulls the runner toward the center of the curve while the centrifugal force pulls away from the center of the curve. To counteract the centrifugal force which tries to lean the runner outward, the runner leans inward. If the direction of rotation of the runner on the track is always counter-clockwise, then the left side is the inside of the track. As a consequence, according to a feature of the present invention, the left side of the right and left prosthetic foot calf shanks can be made thinner than the right side and the amputee runner's curve performance could be improved.

The foot keels 2, 33, 38, 42 and 43 in the several embodiments, are each 29 cm long with the proportions of the shoe 1 shown to scale in Figures 3, 4 and 5, and in the several views of the different calf shanks and foot keels. However, as will be readily understood by the skilled artisan, the specific dimensions of the prosthetic foot can be varied depending on the size, weight and other characteristics of the amputee being fitted with the foot.

The operation of the prosthetic foot 1 in walking and running stance phase gait cycles will now be considered. Newton's three laws of motion, that relate to law of inertia, acceleration and action-reaction, are the basis for movement kinematics in the foot 2. From Newton's third law, the law of action-reaction, it is known that the ground pushes on the foot in a direction equal and opposite to the direction the foot pushes on the ground. These are known as ground reaction forces. Many scientific studies have been done on human gait, running and jumping activities. Force plate studies show us that Newton's third law occurs in gait. From these studies, we know the direction the ground pushes on the foot.

The stance phase of walking/running activities can be further broken down into deceleration and acceleration phases. When the prosthetic foot touches the ground, the foot pushes anteriorly on the ground and the ground pushes back in an equal and opposite direction - that is to say the ground pushes posteriorly on the prosthetic foot.

This force makes the prosthetic foot move. The stance phase analysis of walking and running activities begins with the contact point being the posterior lateral corner 18, Figs. 5 and 8, which is offset more posteriorly and laterally than the medial side of the foot. This offset at initial contact causes the foot to evert and the calf shank to plantar flex. The calf shank always seeks a position that transfers the body weight through its shank, e.g., it tends to have its long vertical member in a position to oppose the ground forces. This is why it moves posteriorly-plantar flexes to oppose the ground reaction force which is pushing posteriorly on the foot.

The ground forces cause calf shanks 44, 45, 46, 47, 50 and 51 to compress with the proximal end moving posterior. With calf shanks 48, 49 the distal 1/2 of the calf shank would compress depending on the distal concavities orientation. If the distal concavity compressed in response to the GRF's the proximal concavity would expand and the entire calf shank unit would move posteriorly. The ground forces cause the calf shank to compress with the proximal end moving posteriorly. The calf shank lower tight radius compresses simulating human ankle joint plantar flexion and the forefoot is lowered by compression to the ground. At the same time to the posterior aspect of keel, as represented by hindfoot 4, depicted by 17 compresses upward through compression. Both of these compressive forces act as shock absorbers. This shock absorption is further enhanced by the offset posterior lateral heel 18 which causes the foot to evert, which also acts as a shock absorber, once the calf shank has stopped moving into plantar flexion and with the ground pushing posteriorly on the foot.

The compressed members of the foot keel and calf shank then start to unload - that is they seek their original shape and the stored energy is released - which causes the calf shank proximal end to move anteriorly in an accelerated manner. As the calf shank approaches its vertical starting position, the ground forces change from pushing posteriorly to pushing vertically upward against the foot. Since the prosthetic foot has posterior and anterior plantar surface weight bearing areas and these areas are connected by a non-weight bearing long arch shaped midportion, the vertically directed forces from the prosthesis cause the long arch shaped midportion to load by expansion.

The posterior and anterior weight-bearing surfaces diverge. These vertically directed forces are being stored in the long arch midportion of the foot - as the ground forces move from being vertical in nature to anteriorly directed. The calf shank expands - simulating ankle dorsiflexion. This causes the prosthetic foot to pivot off of the anterior
5 plantar weight-bearing surface. As weight unloading occurs, the long arch of the midfoot portion 5 changes from being expanded and it seeks its original shape which creates a simulated plantar flexor muscle group burst. This releases the stored vertical compressed force energy into improved expansion capabilities.

The long arch of the foot keel and the calf shank resist expansion of their
0 respective structures. As a consequence, the calf shank anterior progression is arrested and the foot starts to pivot off the anterior plantar surface weight-bearing area. The expansion of the midfoot portion of the foot keel has as high and low response capability in the case of the foot keels in the example embodiments of Figures 3-5 and
5 8, Figures 11 and 12, Figure 13 and Figure 14. Since the midfoot forefoot transitional area of these foot keels is deviated 15° to 35° externally from the long axis of the foot, the medial long arch is longer than the lateral long arch. This is important because in the normal foot, during acceleration or deceleration, the medial aspect of the foot is used.

The prosthetic foot longer medial arch has greater dynamic response
0 characteristic than the lateral. The lateral shorter toe lever is utilized when walking or running at slower speeds. The body's center of gravity moves through space in a sinusoidal curve. It moves medial, lateral, proximal and distal. When walking or running at slower speeds, the body's center of gravity moves more medial and lateral than when walking or running fast. In addition, momentum or inertia is less and the ability to
5 overcome a higher dynamic response capability is less. The prosthetic foot of the invention is adapted to accommodate these principles in applied mechanics.

In addition, in the human gait cycle at midstance the body's center of gravity is as far lateral as it will go. From midstance through toe off the body's center of gravity (BCG) moves from lateral to medial. As a consequence, the body's center of gravity

progresses over the lateral side of the foot keel 2. First (low gear) and as the BCG progresses forward, it moves medially on foot keel 2 (high gear). As a consequence, the prosthetic foot keel 2 has an automatic transmission effect. That is to say, it starts in low gear and moves into high gear every step the amputee takes.

5 As the ground forces push anteriorly on the prosthetic foot which is pushing posteriorly on the ground, as the heel begins to rise the anterior portion of the long arch of the midfoot portion is contoured to apply these posteriorly directed forces perpendicular to its plantar surface. This is the most effective and efficient way to apply these forces. The same can be said about the posterior hindfoot portion of the
0 prosthetic foot. It is also shaped so that the posteriorly directed ground forces at initial contact are opposed with the foot keel's plantar surface being perpendicular to their applied force direction.

In the later stages of heel rise, toe off walking and running activities, the ray region of the forefoot portion is dorsiflexed 15° - 35° . This upwardly extending arc allows
5 the anteriorly directed ground forces to compress this region of the foot. This compression is less resisted than expansion and a smooth transition occurs to the swing phase of gait and running with the prosthetic foot. In later stages of stance phase of gait, the expanded calf shank and the expanded midfoot long arch release their stored energy adding to the propulsion of the amputee's body center of gravity.

0 One of the main propulsion mechanisms in human gait is called the active propulsion phase. As the heel lifts, the body weight is now forward of the support limb and the center of gravity is falling. As the body weight drops over the forefoot rocker Fig. 5, line C-C there is a downward acceleration, which results in the highest vertical force received by the body. Acceleration of the leg forward of the ankle, associated with
5 lifting of the heel, results in a posterior shear against the ground. As the center of pressure moves anterior to the metatarsal heads axis of rotation the effect is an ever-increasing dorsiflexion torque. This creates a full forward fall situation that generates the major progression force used in walking. The signs of effective ankle function

during the active propulsion are heel lift, minimal joint motion, and a nearly neutral ankle position. A stable midfoot is essential for normal sequencing in heel lift.

5 The posterior aspect of the hindfoot and the forefoot region of the foot keel incorporate expansion joint holes and expansion joint struts in several of the embodiments as noted previously. The orientation of the expansion joint holes act as a mitered hinge and biplanar motion capabilities are improved for improving the total contact characteristics of the plantar surface of the foot when walking on uneven terrain.

0 The Symes foot keels in Figures 9-12 are distinctively different in dynamic response capabilities - as these capabilities are associated with walking, running and jumping activities. These foot keels differ in four distinct features. These include the presence of a concavity in the proximate, posterior of the midfoot portion for accommodating the Symes distal residual limb shape better than a flat surface. This concavity also lowers the height of the foot keel which accommodates the longer residual limb that is associated with the Symes level amputee. The alignment concavity
5 requires that the corresponding anterior and posterior radii of the arched foot keel midportion be more aggressive and smaller in size. As a consequence, all of the midfoot long arch radii and the hindfoot radii are tighter and smaller. This significantly affects the dynamic response characteristics. The smaller radii create less potential for a dynamic response. However, the prosthetic foot responds quicker to all of the
0 aforementioned walking, running and jumping ground forces. The result is a quicker foot with less dynamic response.

Improved task specific athletic performance can be achieved with alignment changes using the prosthetic foot of the invention, as these alignment changes affect the vertical and horizontal components of each task. The human foot is a multi-
5 functional unit - it walks, runs and jumps. The human tibia fibula calf shank structure on the other hand is not a multi-functional unit. It is a simple lever which applies its forces in walking, running and jumping activities parallel to its long proximal-distal orientation. It is a non-compressible structure and it has no potential to store energy. On the other hand, the prosthetic foot of the invention has dynamic response capabilities, as these

dynamic response capabilities are associated with the horizontal and vertical linear velocity components of athletic walking, running and jumping activities and out-performing the human tibia and fibula. As a consequence, the possibility exists to improve amputee athletic performance. For this purpose, according to the present invention, the fastener 8 is loosened and the alignment of the calf shank and the foot keel with respect to one another is adjusted in the longitudinal direction of the foot keel. Such a change is shown in connection with Figures 1 and 2. The calf shank is then secured to the foot keel in the adjusted position with the fastener 8. During this adjustment, the bolt of the fastener 8 slides relative to one or both of the opposed, relatively longer, longitudinally extending openings 9 and 10 in the foot keel and calf shank, respectively.

An alignment change that improves the performance characteristic of a runner who makes initial contact with the ground with the foot flat as in a midfoot strike runner, for example, is one wherein the foot keel is slid anterior relative to the calf shank and the foot plantar flexed on the calf shank. This new relationship improves the horizontal component of running. That is, with the calf shank plantar flexed to the foot, and the foot making contact with the ground in a foot flat position as opposed to initially heel contact, the ground immediately pushes posteriorly on the foot that is pushing anteriorly on the ground. This causes the calf shank to move rapidly forward (by expanding) and downwardly. Dynamic response forces are created by expansion which resists the calf shank's direction of initial movement. As a consequence, the foot pivots over the metatarsal plantar surface weight-bearing area. This causes the midfoot region of the keel to expand which is resisted more than compression. The net effect of the calf shank expansion and the midfoot expansion is that further anterior progression of the calf shank is resisted which allows the knee extenders and hip extenders in the user's body to move the body's center of gravity forward and proximal in a more efficient manner (i.e., improved horizontal velocity). In this case, more forward than up than in the case of a heel toe runner whose calf shank's forward progression is less resisted by the calf shank starting more dorsiflexed (vertical) than a foot flat runner.

To analyze the sprint foot in function, an alignment change of the calf shank and foot keel is made. Advantage is taken of the foot keel having all of its concavities with their longitudinal axis orientation parallel to the frontal plane. The calf shank is plantar flexed and slid posterior on the foot keel. This lowers the distal circles even further than on the flat foot runner with the multi-use foot keel like that in Figures 3-5 and 8, for example. As a consequence, there is even greater horizontal motion potential and the dynamic response is directed into this improved horizontal capability.

The sprinters have increased range of motion, forces and momentum (inertia) - momentum being a prime mover. Since their stance phase deceleration phase is shorter than their acceleration phase, increased horizontal linear velocities are achieved. This means that at initial contact, when the toe touches the ground, the ground pushes posteriorly on the foot and the foot pushes anteriorly on the ground. The calf shank which has increased forces and momentum is forced into even greater flexion and downward movement than the initial contact foot flat runner. As a consequence to these forces, the foot's long arch concavity is loaded by expansion and the calf shank is loaded by expansion. These expansion forces are resisted to a greater extent than all the other previously mentioned forces associated with running. As a consequence, the dynamic response capability of the foot is proportional to the force applied. The human tibia fibula calf shank response is only associated with the energy force potential - it is a straight structure and it cannot store energy. These expansion forces in the prosthetic foot of the invention in sprinting are greater in magnitude than all the other previously mentioned forces associated with walking and running. As a consequence, the dynamic response capability of the foot is proportional to the applied forces and increased amputee athletic performance, as compared with human body function, is possible.

The prosthetic foot 53 depicted in Fig. 25 is like that in Fig. 3 except for the adjustable fastening arrangement between the calf shank and the foot keel and the construction of the upper end of the calf shank for connection to the lower end of a pylon. In this example embodiment, the foot keel 54 is adjustably connected to the calf

shank 55 by way of plastic or metal alloy coupling element 56. The coupling element is attached to the foot keel and calf shank by respective releasable fasteners 57 and 58 which are spaced from one another in the coupling element in a direction along the longitudinal direction of the foot keel. The fastener 58 joining the coupling element to the calf shank is more posterior than the fastener 57 joining the foot keel and the coupling element. By increasing the active length of the calf shank in this way, the dynamic response capabilities of the calf shank itself are increased. Changes in alignment are made in cooperation with longitudinally extending openings in the calf shank and foot keel as in other example embodiments.

The upper end of the calf shank 55 is formed with an elongated opening 59 for receiving a pylon 15. Once received in the opening, the pylon can be securely clamped to the calf shank by tightening bolts 60 and 61 to draw the free side edges 62 and 63 of the calf shank along the opening together. This pylon connection can be readily adjusted by loosening the bolts, telescoping the pylon relative to the calf shank to the desired position and reclamping the pylon in the adjusted position by tightening the bolts.

The prosthetic foot 70 according to a further embodiment of the invention is depicted in Figs. 28-31B. The prosthetic foot 70 comprises a foot keel 71, a calf shank 72 and a coupling element 73. The prosthetic foot 70 is similar to the prosthetic foot 53 in the embodiment of Figs. 25-27, except that the calf shank 72 is formed with a downward, anteriorly facing convexly curved lower end 74 which is in the form of a spiral 75. The calf shank extends upward anteriorly from the spiral to an upstanding upper end thereof as seen in Fig. 28. The calf shank can be advantageously formed of metal, such as titanium, but other resilient materials could be used to form the semi-rigid, resilient calf shank.

The spiral shape at the lower end of the calf shank has a radius of curvature which progressively increases as the calf shank spirals outwardly from a radially inner end 76 thereof and as the calf shank extends upwardly from its lower, spiral end to its upper end, which may be curved or straight. It has been found that this construction

creates a prosthetic foot with an integrated ankle and calf shank with a variable radii response outcome similar to the parabola shaped calf shank of the invention, while at the same time allowing the coupling element 73 and calf shank 72 to be more posterior on the foot keel 71. As a result, the calf shank and coupling element are more centrally concealed in the ankle and leg of a cosmetic covering 77, see Fig. 28.

The coupling element 73 is formed of plastic or metal alloy, and is adjustably fastened at its anterior end to the posterior of foot keel 71 by a threaded fastener 78 as shown in Fig. 30. The foot keel has a longitudinally extending opening 79 in an upwardly arched portion thereof which receives the fastener 78 to permit adjusting the alignment of the calf shank and foot keel with respect to one another in the longitudinal direction, e.g. along the line 30-30 in Fig. 29, in the manner explained above in connection with the other embodiments.

The posterior end of the coupling element includes a cross member 80 which is secured between two longitudinally extending plates 81 and 82 of the coupling element by metal screws 83 and 84 at each end of the cross member. The radially inner end 76 of the spiral 75 is secured to the cross member 80 of the coupling element by a threaded fastener 85 as depicted in Fig. 30. From its point of connection to the cross member, the calf shank spirals around the radially inner end 76 above the heel portion of the foot keel and extends upward anteriorly from the spiral through an opening 85 through the coupling element between plates 81 and 82 anterior of the cross member 80. A cross member 86 in the anterior end of coupling element 73 is secured between plates 81 and 82 by fasteners 87 and 88 at each end as seen in Figs. 28 and 30. The fastener 78 is received in a threaded opening in cross member 86.

The posterior surface of the cross member 86 supports a wedge 87 formed of plastic or rubber, for example, which is adhesively bonded at 88 to the cross member. The wedge serves as a stop to limit dorsiflexion of the upwardly extending calf shank in gait. The size of the wedge can be selected, wider at 87' in Fig. 31A, or narrower at 87" in Fig. 31B, to permit adjustment of the desired amount of dorsiflexion. A plurality of the

wedges could be used at once, one atop another and adhesively bonded to the coupling element for reducing the permitted dorsiflexion.

A prosthetic socket, not shown, attached to the amputee's lower leg stump can be connected to the upper end of calf shank 72 via an adapter 88 secured to the upper
5 end of the calf shank by fastener 89 and 90 as shown in Fig. 28. The adapter has an inverted pyramid-shaped attachment fitting 91 connected to an attachment plate attached to an upper surface of the adapter. The pyramid fitting is received by a complementarily shaped socket-type fitting on the depending prosthetic socket for joining the prosthetic foot and prosthetic socket.

10 This concludes the description of the example embodiments. Although the present invention has been described with reference to a number of illustrative embodiments, it should be understood that numerous other modifications and embodiments can be devised by those skilled in the art that will fall within the spirit and scope of the principles of this invention. For example, the lower end of the calf shank in
15 the prosthetic foot of the invention is not limited to a parabola shape or a generally parabola shape or a spiral shape but can be otherwise downward convexly, curvilinearly configured to produce the desired motion outcomes of the foot when connected to the foot keel to form the ankle joint area of the foot. The features of the various
20 embodiments could also be used with one another. More particularly, reasonable variations and modifications are possible in the component parts and/or arrangements of the subject combination arrangement within the scope of the foregoing disclosure, the drawings, and the appended claims without departing from the spirit of the invention. In addition to variations and modifications in the component parts and/or arrangements, alternative uses will also be apparent to those skilled in the art.

What is claimed is:

1. A prosthetic foot comprising:
a longitudinally extending foot keel;
a calf shank secured to the foot keel at a lower end thereof and extending upwardly from the foot keel;
wherein the lower end of the calf shank is in the form of a spiral, the calf shank extending upward anteriorly from the spiral to an upstanding upper end thereof.
2. The prosthetic foot according to claim 1, wherein the calf shank is secured to the foot keel by way of a coupling element.
3. The prosthetic foot according to claim 2, wherein a radially inner end of the spiral of the calf shank is fastened to the coupling element.
4. The prosthetic foot according to claim 3, wherein the calf shank lower end spirals around the radially inner end above the foot keel.
5. The prosthetic foot according to claim 1 wherein the coupling element includes a stop to limit dorsiflexion of the upwardly extending calf shank in gait.
6. The prosthetic foot according to claim 5, wherein said stop includes at least one wedge shaped member secured to the coupling element anterior of the calf shank.
7. The prosthetic foot according to claim 1, wherein the calf shank is secured to the posterior of the foot keel and extends upwardly above a hindfoot portion and the posterior part of a midfoot portion of the foot keel.

8. The prosthetic foot according to claim 1, further comprising a cosmetic covering in the shape of a human foot and lower leg, the cosmetic covering being located over the foot keel and at least the lower end of the calf shank with the calf shank rising upwardly from the foot keel within the lower leg covering.

9. The prosthetic foot according to claim 1, further comprising an adjustable fastening arrangement securing the calf shank to the foot keel, the fastening arrangement permitting adjustment of the relationship of the foot keel and calf shank to tune the performance of the prosthetic foot.

10. The prosthetic foot according to claim 9, wherein the adjustable fostering arrangement includes at least one releasable fastener and a longitudinally extending opening in the foot keel through which the fastener extends to permit adjustment of the alignment of the calf shank and the foot keel in the longitudinal direction of the foot keel.

11. The prosthetic foot according to claim 1, wherein the calf shank has a radius of the curvature which increases progressively as the calf shank spirals outwardly and as the calf shank extends upwardly from its lower, spiral end.

12. The prosthetic foot according to claim 1, wherein the foot keel has an upward convexly curved dorsal surface of a midfoot portion of the foot keel facing the spiral lower end of the calf shank, radii of curvature of the spiral and the convexly curved dorsal surface of the foot keel affecting a dynamic response capability and motion outcome of the prosthetic foot in gait.

13. A prosthetic foot comprising:
a longitudinally extending foot keel;
a coupling element connected to the foot keel;

a resilient, upstanding calf shank having a lower end connected to the foot keel by way of the coupling element to form an ankle joint area of the foot, and an upper end to connect with a supporting structure on an amputee's leg;

wherein the lower end of the calf shank is in the form of a spiral, the calf shank extending upwardly anteriorly from the spiral to the upper end thereof.

14. The prosthetic foot according to claim 13, wherein the coupling element includes a stop to limit dorsiflexion of the calf shank in gait.

15. The prosthetic foot according to claim 14, wherein the stop includes at least one wedge shaped member secured to the coupling element anterior of the calf shank.

16. The prosthetic foot according to claim 13, further comprising an adjustable fastening arrangement to permit adjustment of the alignment of the calf shank and the foot keel with respect to one another in the longitudinal direction of the foot keel for tuning the performance of the prosthetic foot.

17. The prosthetic foot according to claim 16, wherein the adjustable fastening arrangement includes at least one releasable fastener connecting the foot keel and the coupling element and a longitudinally extending opening in the foot keel through which the fastener extends to permit said adjustment of the alignment of the foot keel and the calf shank.

18. The prosthetic foot according to claim 13, wherein the spiral lower end of the calf shank has a radius of curvature which increases progressively as the calf shank spirals and as it extends upwardly from its spiral lower end.

19. The prosthetic foot according to claim 13, further comprising a cosmetic covering in the shape of a human foot and lower leg, the cosmetic covering being located over the foot keel and at least the lower end of the calf shank with the calf shank rising upwardly from the foot keel within the lower leg covering.

20. A calf shank for a prosthetic foot comprising:
an elongated, semi-rigid resilient member having one end in the form of a spiral for attachment to a foot keel to form an ankle joint area of the prosthetic foot, and an opposite end for connection with a supporting structure on an amputee's leg, the member extending curvilinearly with a progressively increasing radius of curvature from the spiral at the one end toward said opposite end.

21. The calf shank according to claim 20, wherein a radially inner end of the spiral at said one end of the member includes a fastener for fastening the calf shank to a coupling element for attachment to a foot keel.

22. The calf shank according to claim 21, wherein the one end of the member spirals around the radially inner end before extending toward the opposite end.

23. The calf shank according to claim 20, wherein the opposite end of the member includes an adapter secured thereto and an inverted pyramid-shaped attachment fitting mounted thereon.

FIG. 1

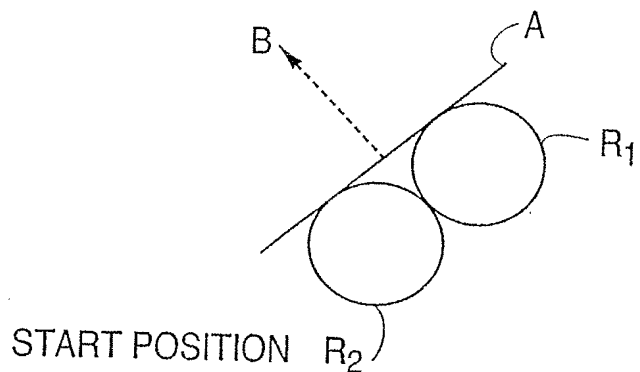


FIG. 2

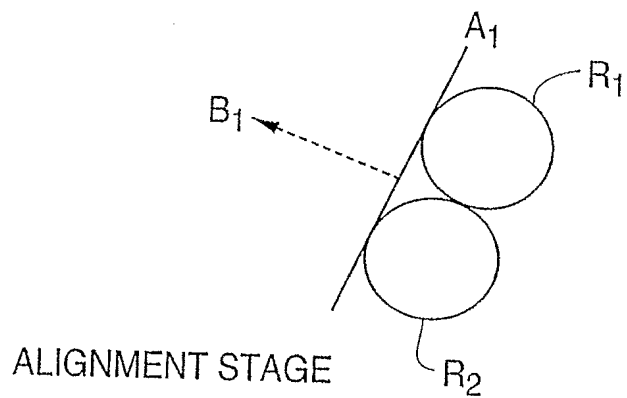


FIG. 3

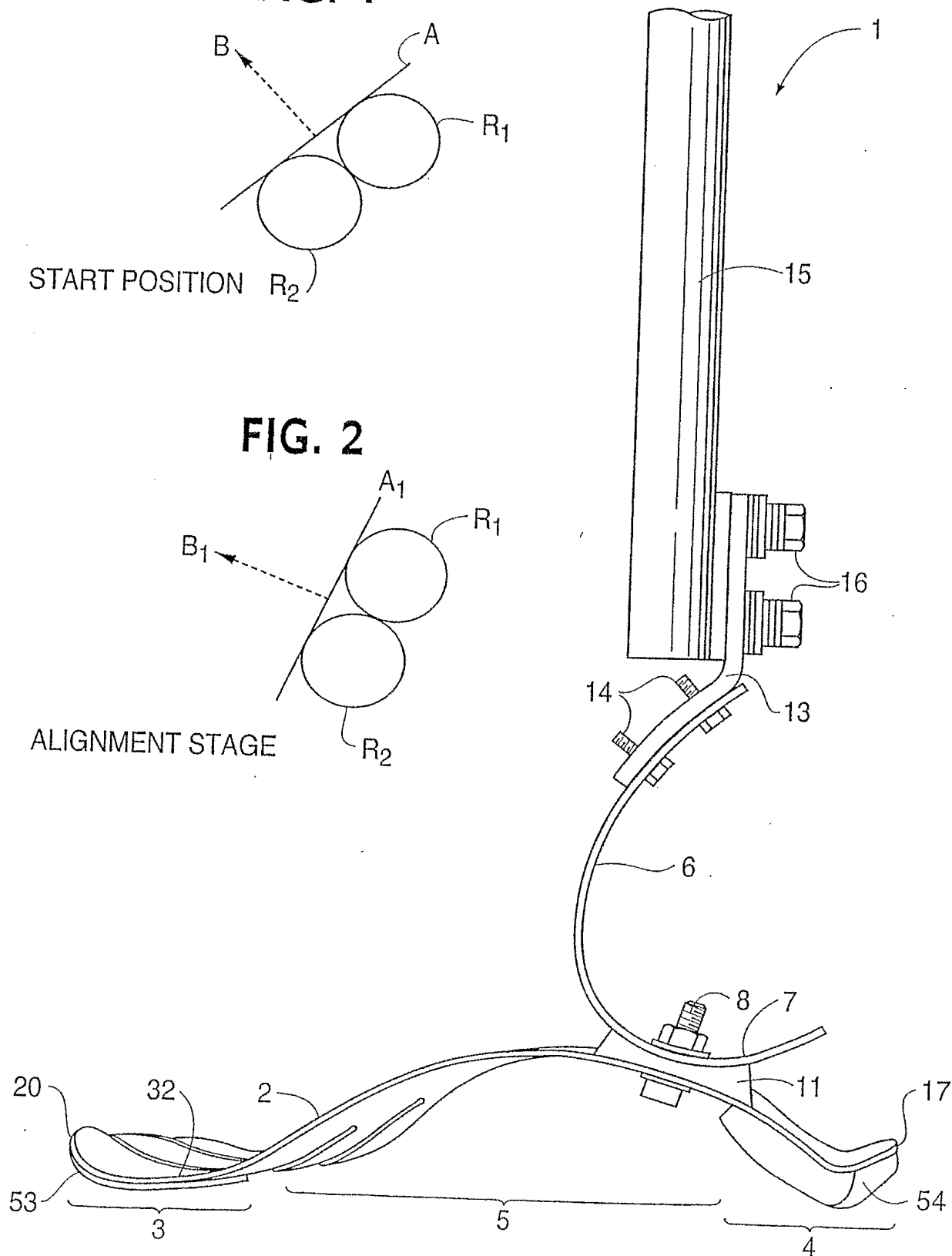


FIG. 4

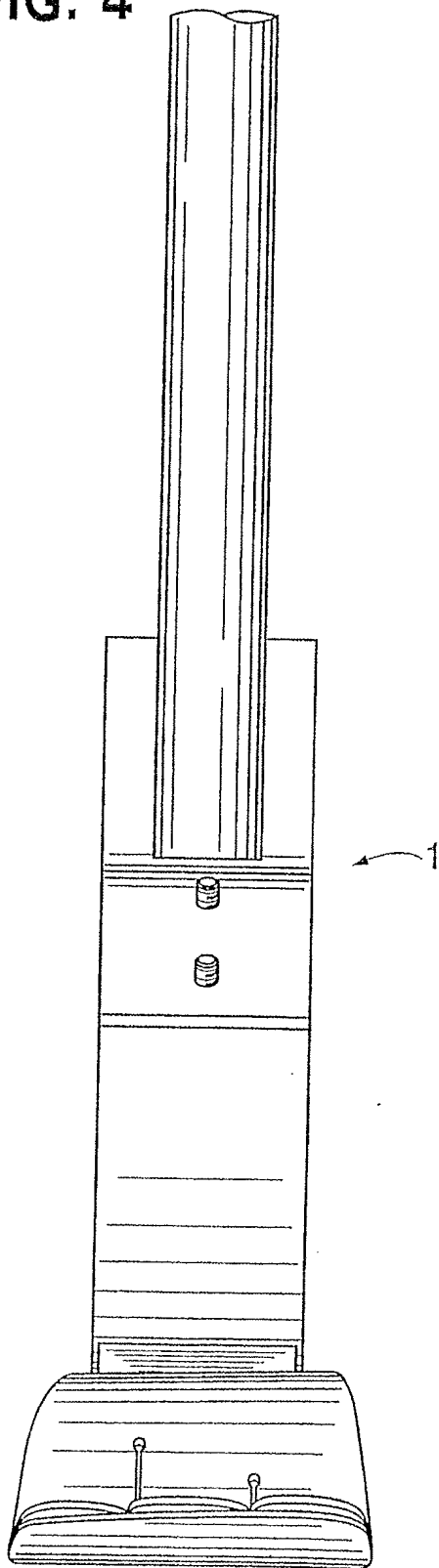
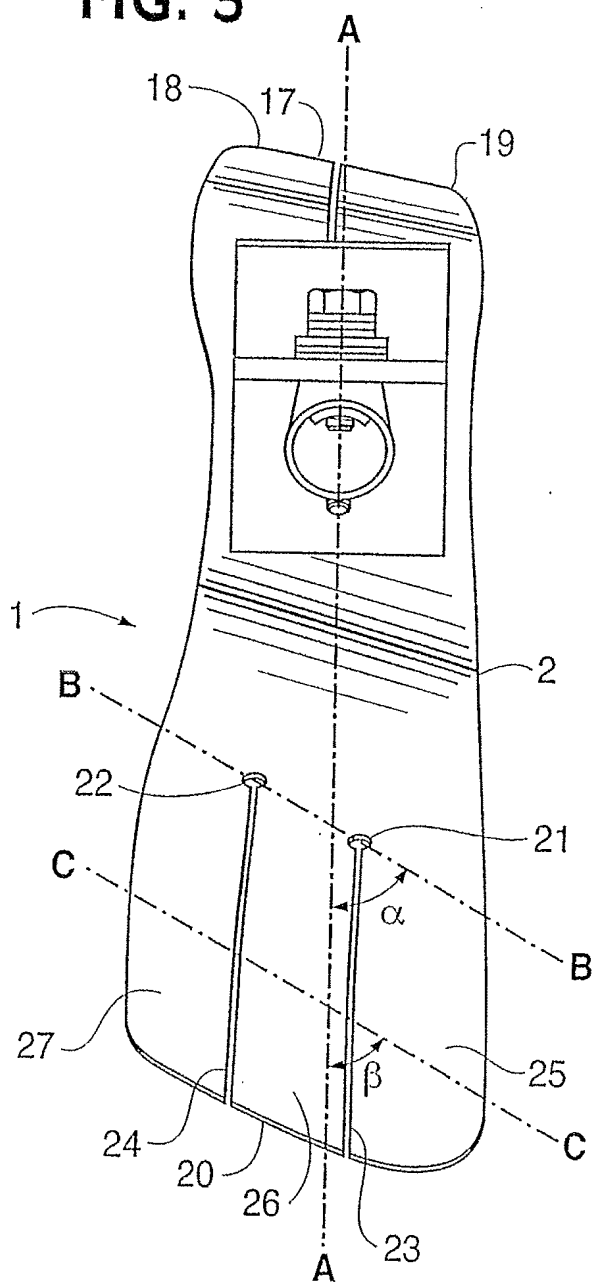


FIG. 5



3/11

FIG. 6

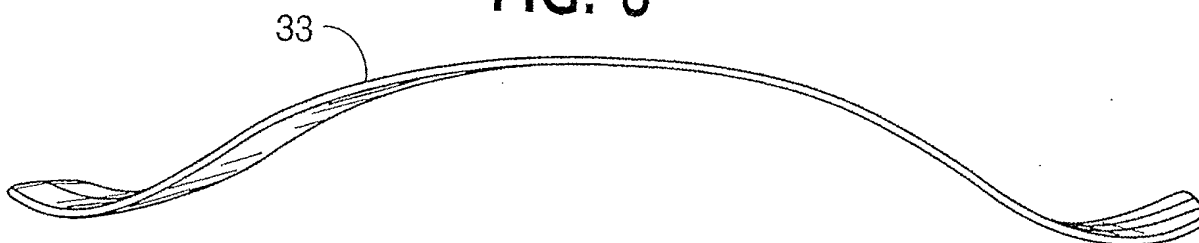


FIG. 7

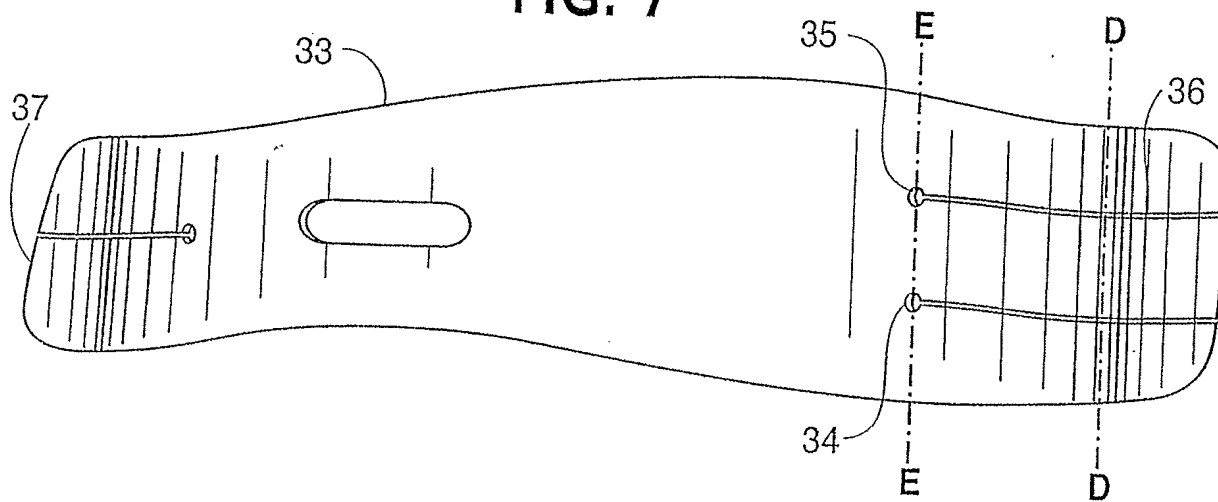
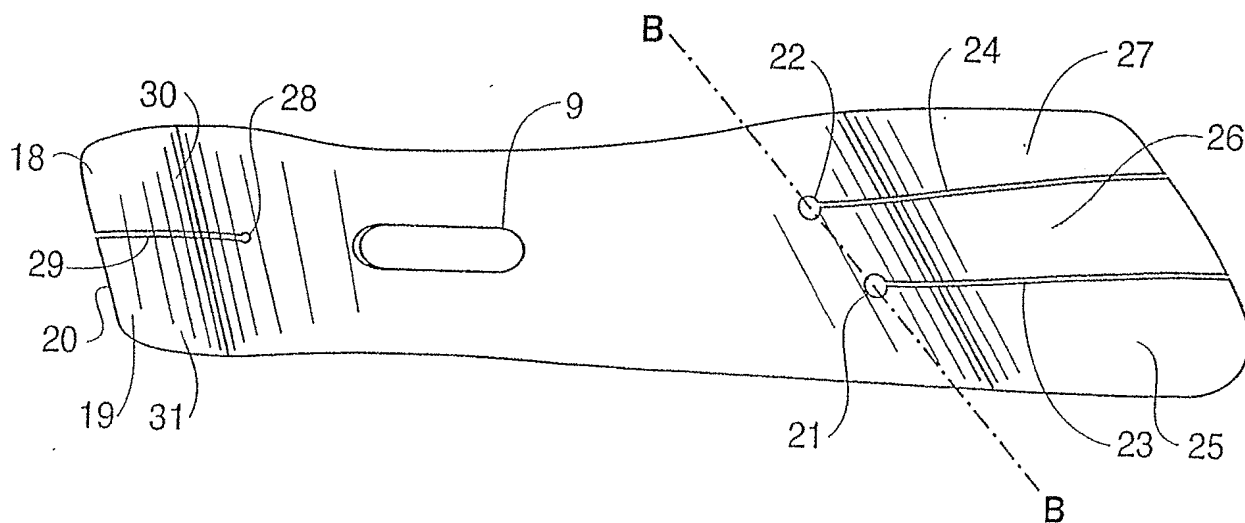


FIG. 8



4/11

FIG. 9

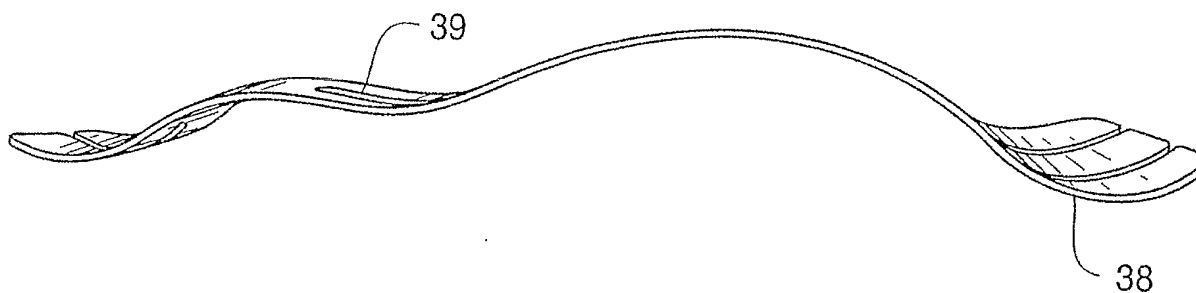


FIG. 10

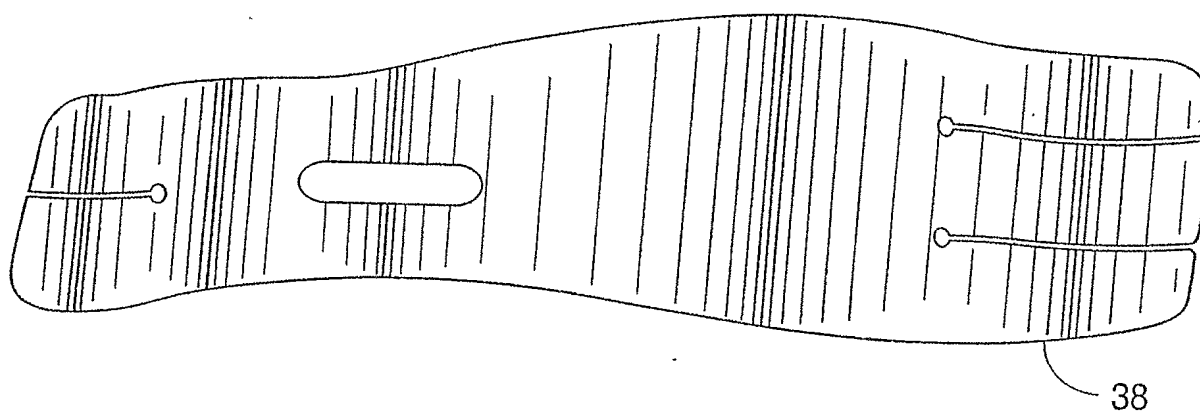


FIG. 11

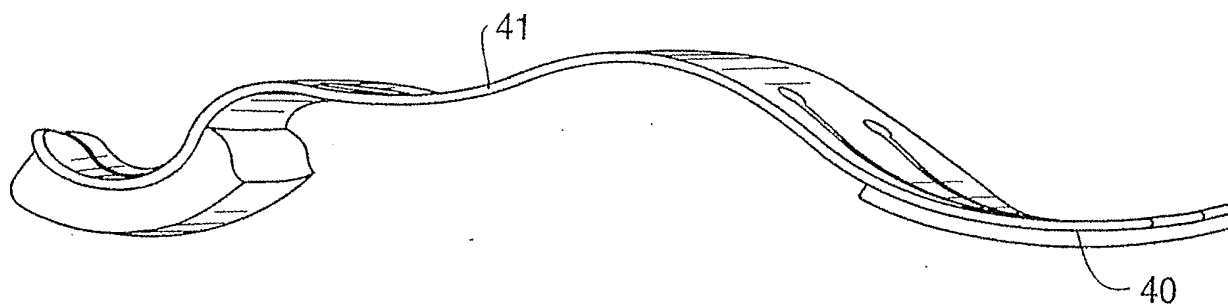
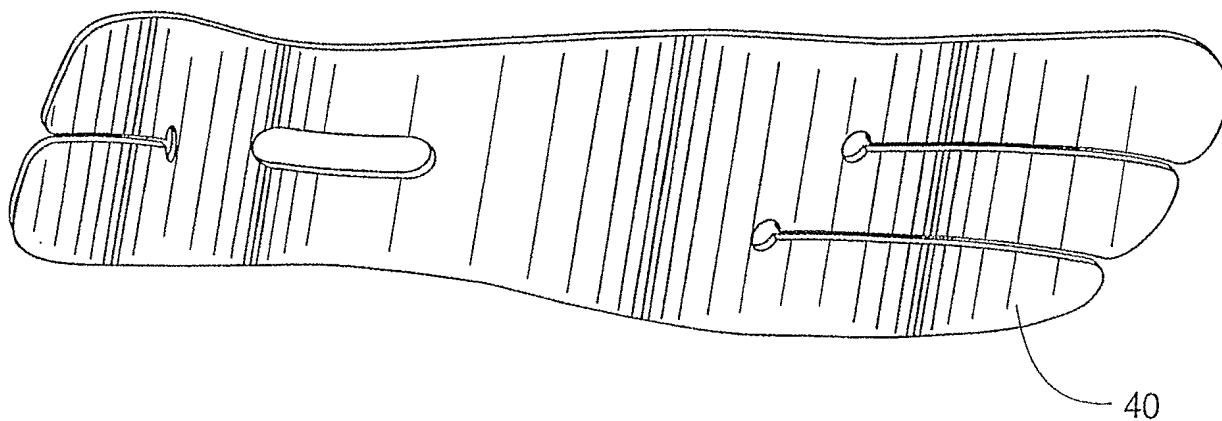


FIG. 12



5/11

FIG. 13

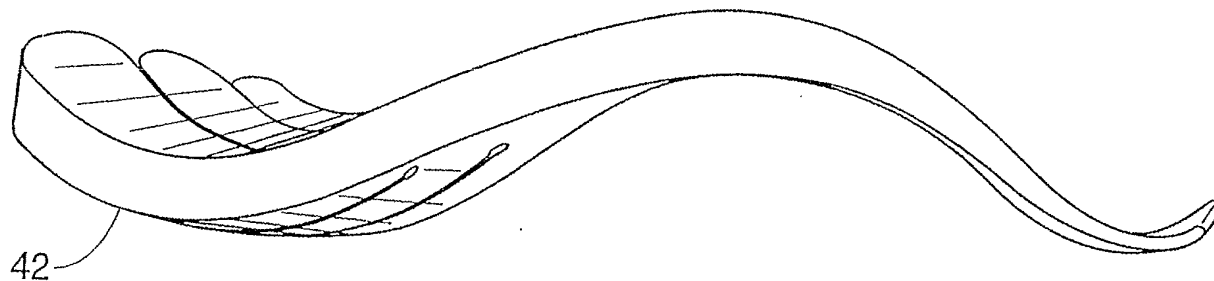


FIG. 14

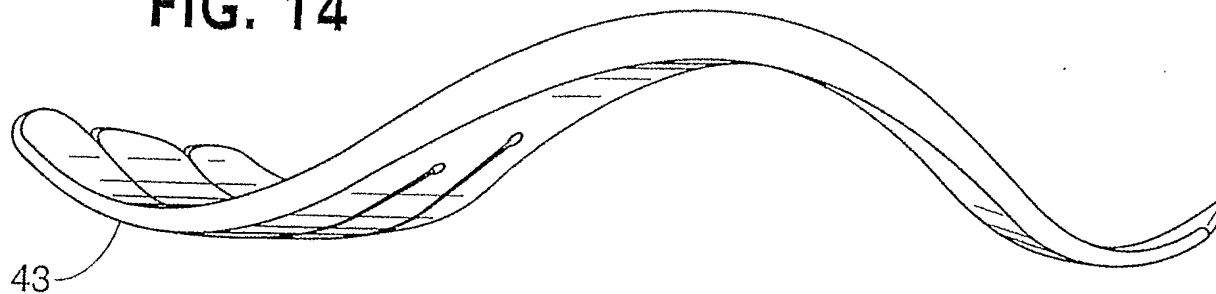


FIG. 15

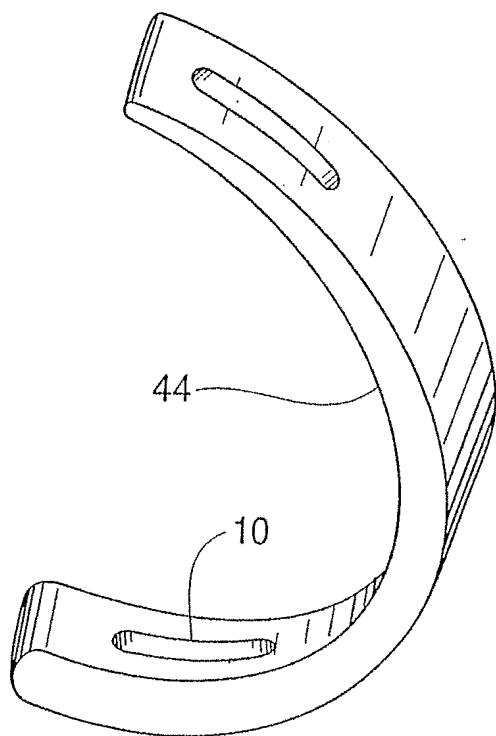
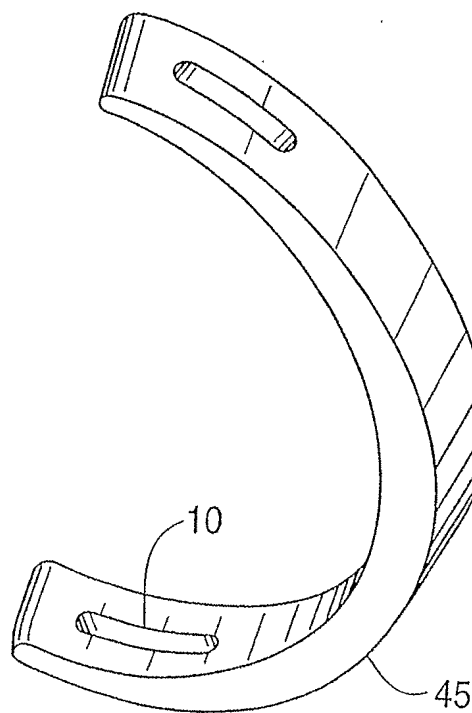


FIG. 16



6/11

FIG. 17

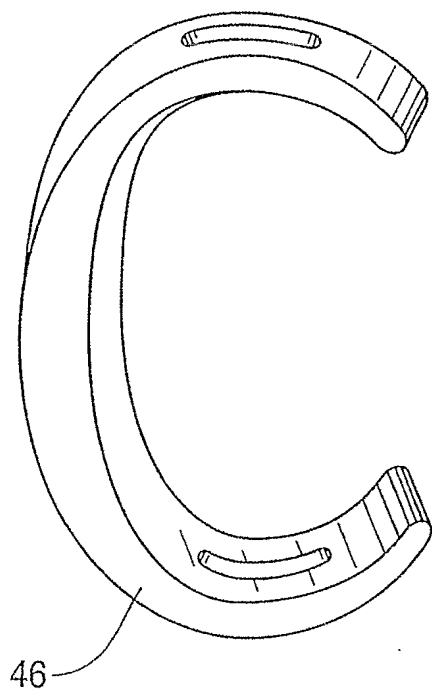


FIG. 18

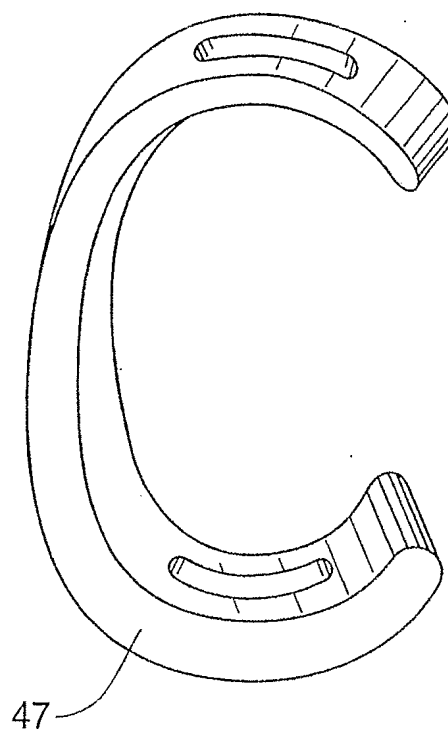


FIG. 19

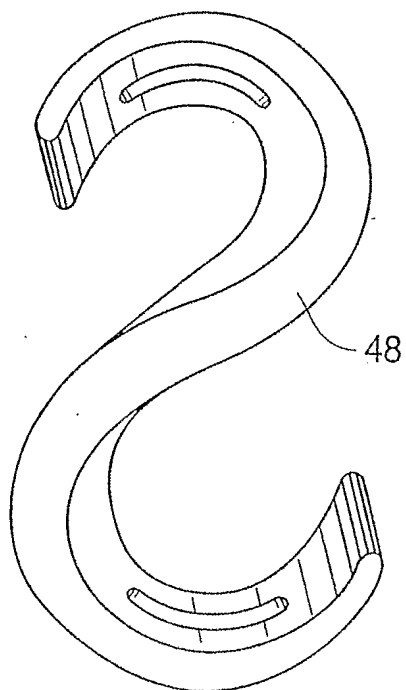
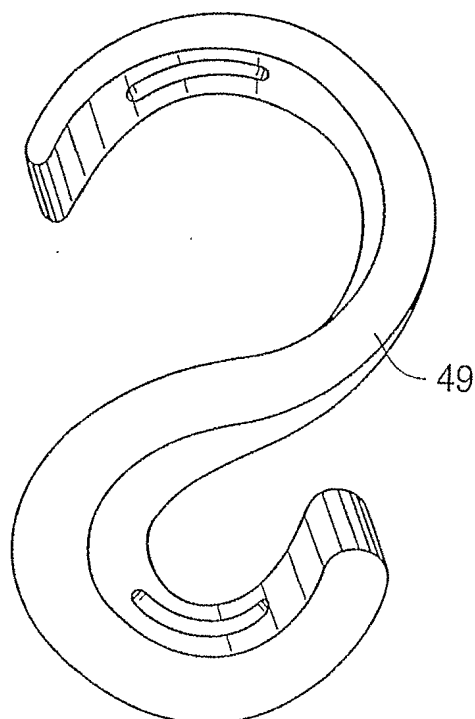


FIG. 20



7/11

FIG. 21

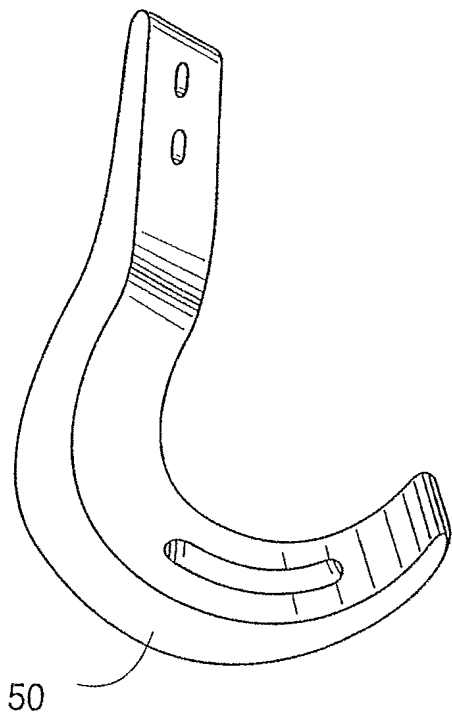


FIG. 22

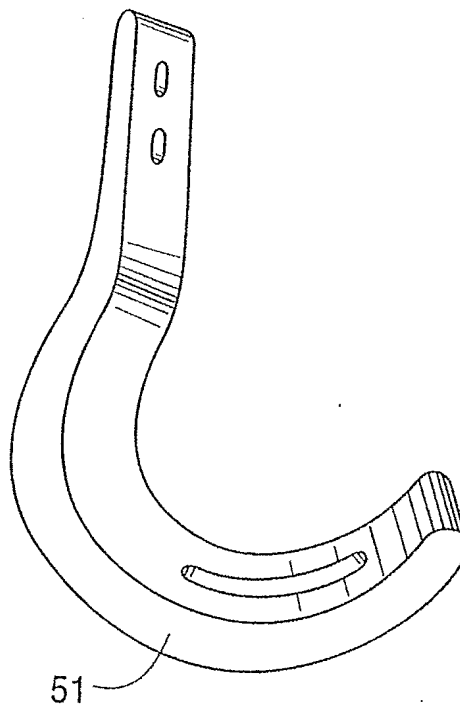


FIG. 23

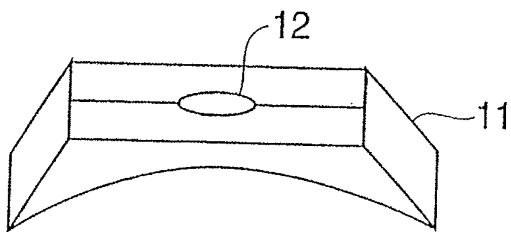
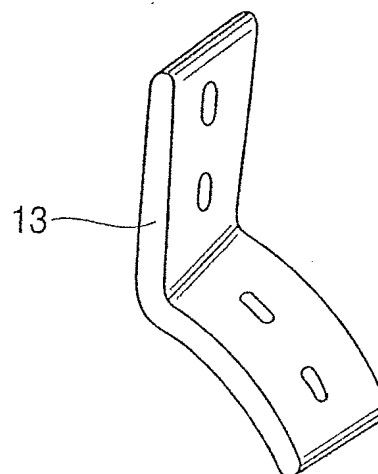
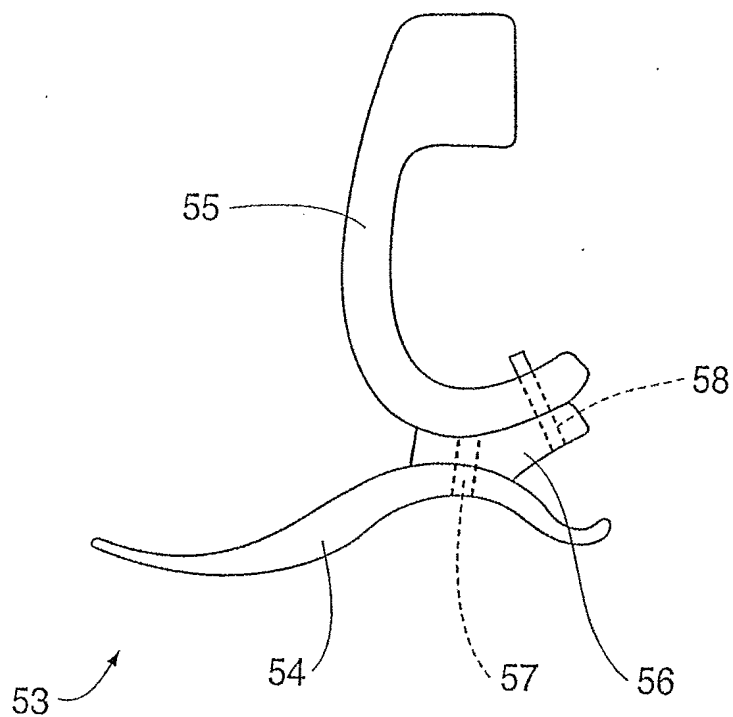
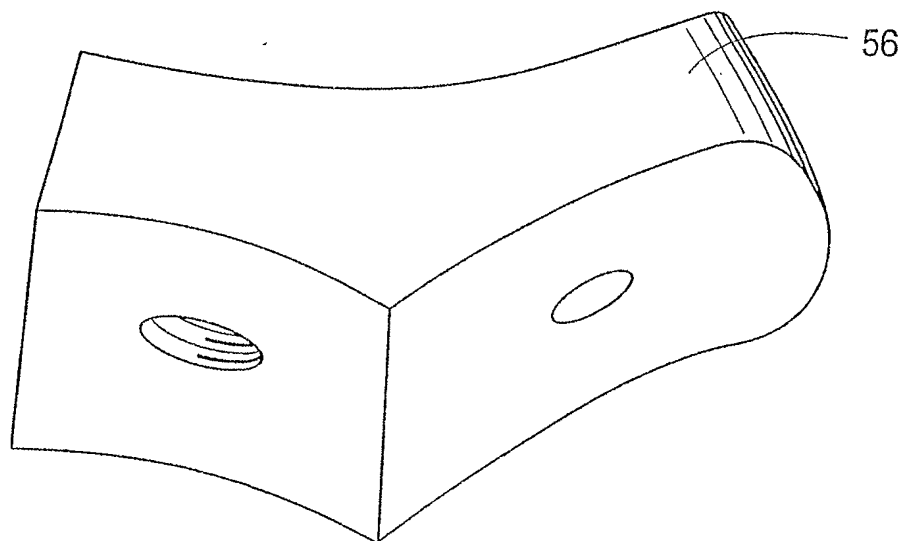


FIG. 24

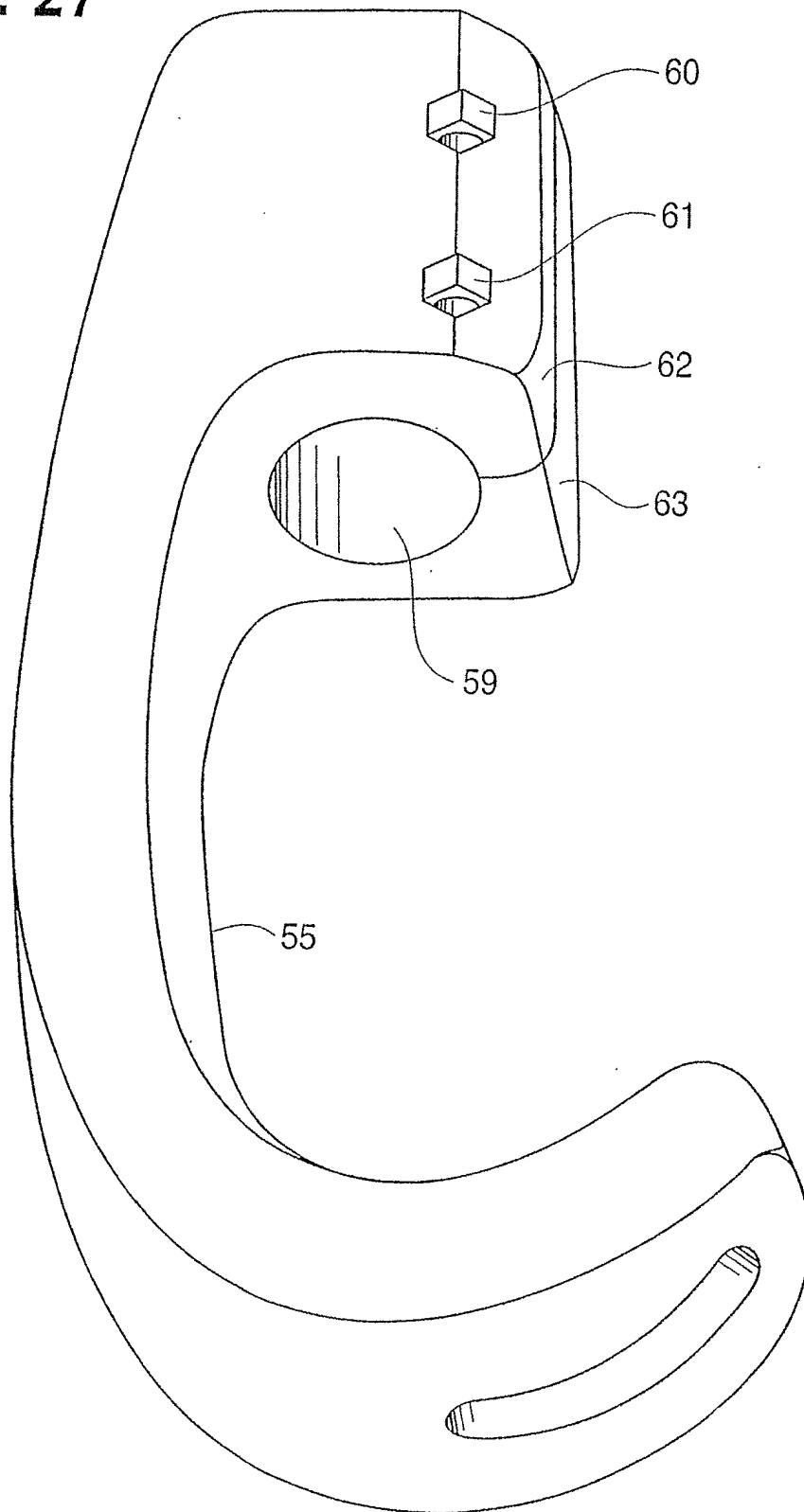


8/11

FIG. 25**FIG. 26**

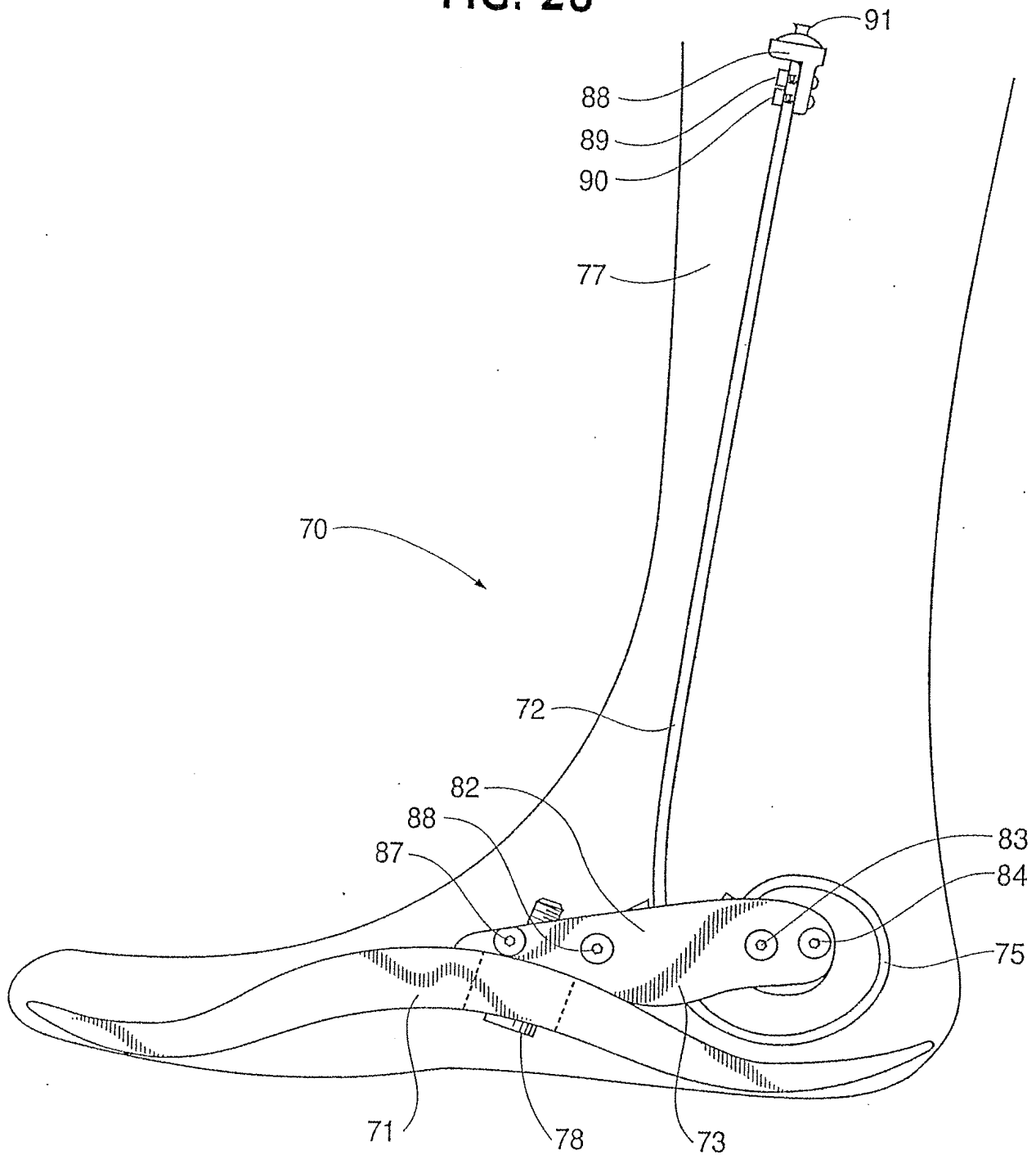
9/11

FIG. 27



10/11

FIG. 28



11/11

FIG. 29

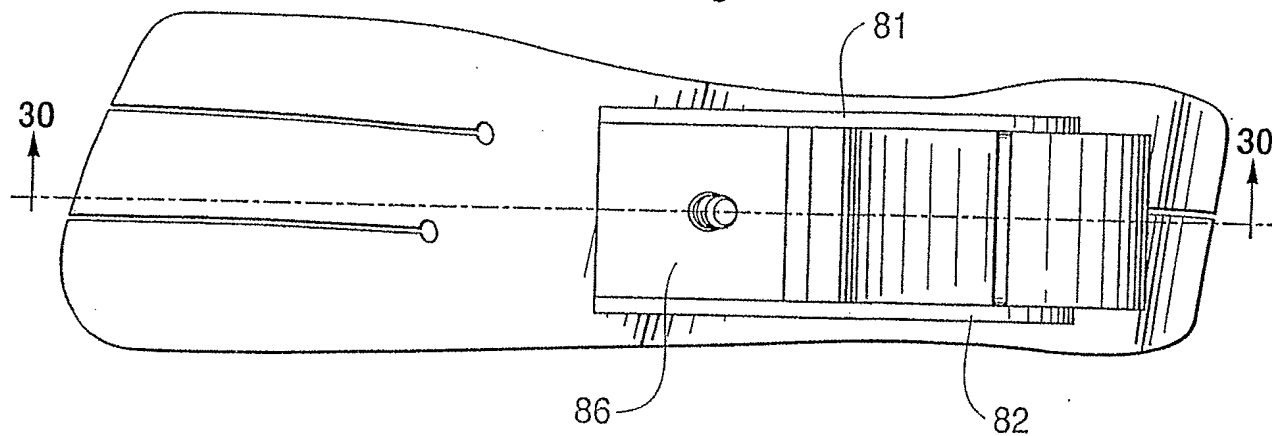


FIG. 30

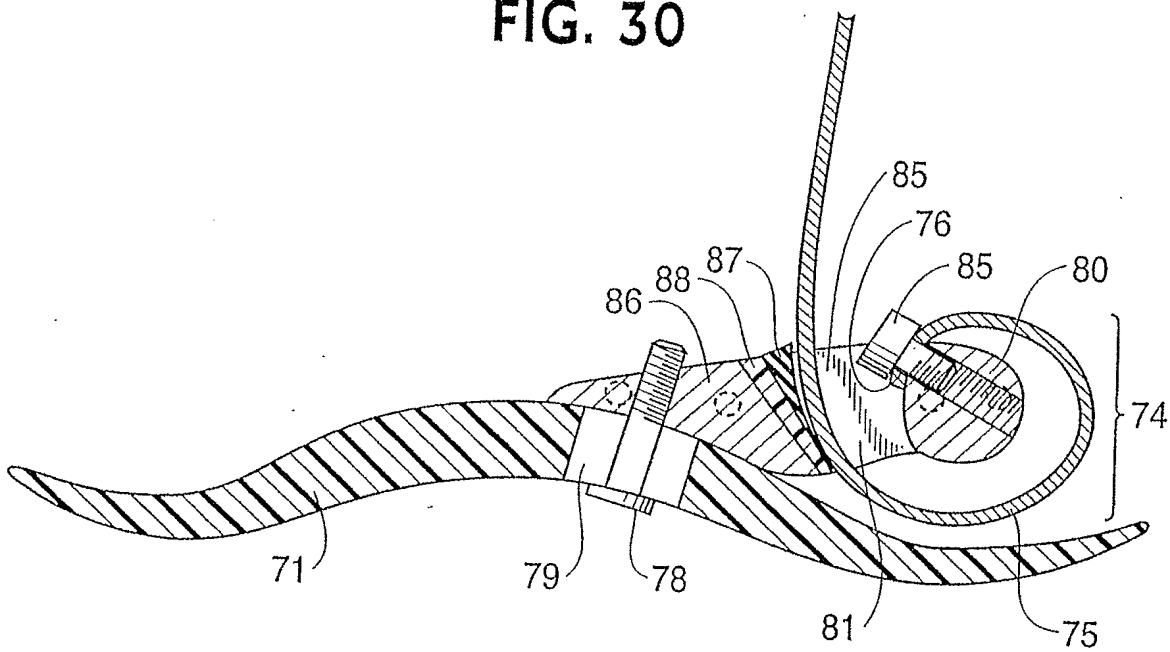
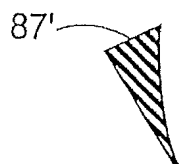


FIG. 31A

FIG. 31B



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/30471

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/68

US CL : 623/28, 38, 49, 52, 55

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/28, 38, 49, 52, 55

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
noneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,897,594 A (MARTIN et al) 27 April 1999, see c-shape element 24.	1-23
A	US 5,653,768 A (KANIA) 50 August 1997, see all embodiments and figures.	1-23
A	US 5,549,714 A (PHILLIPS) 27 August 1996, see resilient member 50 having a U-shaped portion 68.	1-23
A	US 4,959,073 A (MERLETTE) 25 September 1990, see resilient member 10 having a curved portion 16.	1-23
A	US 5,458,656 A (PHILLIPS) 17 October 1995, see all embodiments and see figure 8, helical spring 62.	1-23

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

• Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

09 JANUARY 2003

Date of mailing of the international search report

09 MAY 2003

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/30471

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,376,139 A (PITKIN) 27 December 1994, see resilient member 1 having varying curved portions.	1-23